

Food and Drug Administration, HHS

§21.65

respect to records compiled by the Food and Drug Administration in a criminal law enforcement investigation where the conduct of the investigation would be prejudiced by such procedures.

(b) Records in the following Food and Drug Administration Privacy Act Record Systems that concern individuals who are subject to Food and Drug Administration enforcement action and consist of investigatory records compiled for law enforcement purposes, including criminal law enforcement purposes, are exempt under 5 U.S.C. 552a(j)(2) and (k)(2) from the provisions enumerated in paragraph (a) of this section:

(1) Bio-research Monitoring Information System—HHS/FDA/09-10-0010.

(2) Regulated Industry Employee Enforcement Records—HHS/FDA/ACMO/09-10-002.

(3) Employee Conduct Investigative Records—HHS/FDA/ACMO/09-10-0013.

(c) The system described in paragraph (b)(3) of this section includes investigatory records compiled solely for the purpose of determining suitability, eligibility, or qualification for Federal civilian employment, military service, Federal contracts, and access to classified information. These records are exempt from disclosure under 5 U.S.C. 552a(k)(5) to the extent that the disclosure would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished after September 27, 1975. Any individual who is refused access to a record that would reveal a confidential source shall be advised in a general way that the record includes information that would reveal a confidential source.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8459, Jan. 27, 1981; 50 FR 52278, Dec. 23, 1985]

§21.65 Access to records in exempt systems.

(a) Where a Privacy Act Record System is exempt and the requested records are unavailable under §21.61, an individual may nevertheless make a request under §21.40 for notification concerning whether any records about him

exist and request access to such records where they are retrieved by his name or other personal identifier.

(b) An individual making a request under paragraph (a) of this section;

(1) May be given access to the records where available under part 20 of this chapter (the public information regulations) or the Commissioner may, in his discretion, entertain a request under any or all of the provisions of §§21.40 through 21.54; and

(2) Shall be given access upon request if the records requested are subject to 5 U.S.C. 552a(k)(2) and not to 5 U.S.C. 552a(j)(2) (i.e., because they consist of investigatory material compiled for law enforcement purposes other than criminal law enforcement purposes) and maintenance of the records resulted in denial to the individual of any right, benefit, or privilege to which he would otherwise be entitled by Federal law, or for which he would otherwise be eligible. An individual given access to a record under this paragraph (b)(2) is not entitled to seek amendment under subpart E of this part. The FDA may refuse to disclose a record that would reveal the identity of a source who furnished information to the Government under a promise of confidentiality, which must be an express promise if the information was furnished on or after September 27, 1975. Any individual refused access to a record that would reveal a confidential source shall be advised in a general way that the record contains information that would reveal a confidential source.

(c) The Commissioner shall not make available any record that is prohibited from public disclosure under §20.82(b) of this chapter.

(d) Discretionary disclosure of a record pursuant to paragraph (b)(1) of this section shall not set a precedent for discretionary disclosure of a similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record in a system that is exempt under §21.61.